

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Karen Williams  
Magistrate Judge

Honorable Thomas Vanaskie  
(Ret.),  
Special Discovery Master

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**ORDER GRANTING IN  
PART AND DENYING IN  
PART MOTION TO  
SEAL PURSUANT TO  
L.CIV.R. 5.3**

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3 (the “Motion to Seal,” ECF No. 859<sup>1</sup>) filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), Princeton Pharmaceutical Inc. (“Princeton”), Huahai U.S. Inc. (“Huahai U.S.”), and Solco Healthcare US, LLC (“Solco,” and collectively with ZHP and Princeton, “the ZHP Parties”) on notice to liaison counsel for Plaintiffs; and each of the twenty-nine documents that the ZHP Parties seek to seal having been carefully considered in the context of the parties’ submissions, the factors contained in Local Civil Rule 5.3(c)(2), and the applicable case law; and the standards set forth therein having been found to have been met as to five documents but not as to the other twenty-four documents at issue, the following Findings<sup>2</sup> are made:

### **FINDINGS**

1. As is typical in litigation of this nature, the parties negotiated the terms of an agreed-upon order to maintain the confidentiality of any materials so designated by a party. On June 26, 2019, the Honorable Robert B. Kugler entered the agreed-upon self-executing “Confidentiality and Protective Order” (the “Protective Order”) (ECF No. 139).

2. The Protective Order permits the producing party to safeguard

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<sup>1</sup> Throughout this Order, the designation “ECF No. \_\_\_\_” shall refer to the document number of a particular filing in the Court’s ECF system.

<sup>2</sup> The parties have complied with the directive in Local Rule 5.3(c) to submit Proposed Findings of Fact and Conclusions of Law. The detailed submissions of the parties were of great value in preparing this Order.

or “RESTRICTED CONFIDENTIAL INFORMATION.” If a document does not contain one of these designations, then the information contained therein may be considered publicly accessible.

3. The Protective Order defines the type of information that warrants a confidentiality designation:

The term “CONFIDENTIAL INFORMATION” as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.

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“RESTRICTED CONFIDENTIAL INFORMATION” means Documents that a Party has designated as “RESTRICTED CONFIDENTIAL” in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm . . .

(ECF No. 139, ¶¶ 9(B), (M).)

4. Recognizing that in a case such as this nature, complexity, and business sensitivity, liberal designation of documents as confidential is anticipated, the Protective Order states that “nothing herein shall be construed to prevent a Producing Party from designating documents as ‘CONFIDENTIAL INFORMATION’ in order to expedite the flow of discovery and to facilitate discovery. . . .” (*Id.* ¶ 9(B)).

5. Pursuant to the Protective Order a party may designate a document as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. *Id.* ¶¶ 22, 24. Disclosure of information designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” other than in accordance with the Order may subject the disclosing person to sanctions. *Id.* ¶ 26.

6. The Protective Order provides that a receiving party may serve a written objection to a confidentiality designation, in which event the producing party is to provide a written justification for the designation within twenty-one days. If the producing party does not make a timely written response, “the challenged designation will be deemed to be void.” *Id.* ¶ 20(a).

7. The Protective Order also establishes the procedures to be followed when material designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” is submitted as part of a court filing. Specifically, the Protective Order provides that “[w]here the filing

party has not had an opportunity to confer with the Producing Party, in advance of a filing, the filing party shall not attach materials containing ‘PROTECTED INFORMATION’ to its filing but shall instead designate by Bates number the materials containing ‘PROTECTED INFORMATION’ that would have been attached or completely redact all ‘PROTECTED INFORMATION’ from such materials.” *Id.* The Protective Order then requires the filing and producing parties to confer “to determine whether they can agree upon non-confidential redacted or excerpted pages of materials containing ‘PROTECTED INFORMATION’ to attach to the filing in place of the Bates number designations or redacted materials.” *Id.* If the parties are unable to agree, “the designating party must file a motion to seal the materials containing ‘PROTECTED INFORMATION’ pursuant to the requirements for doing so as set forth in Local Rule 5.3(c), and within thirty (30) days of the completion of briefing related to the original motion, or else waive confidentiality as to the materials containing ‘PROTECTED INFORMATION’ at issue.” *Id.*

8. The ZHP Parties, as the designating party, have moved to seal twenty-nine documents, all but one of which has been presented to the Court as part of filing made by Plaintiffs.<sup>3</sup> The ZHP Parties did not move to seal the court filings to which the documents in question are attached, one of which, Doc. 685, was redacted substantially.<sup>4</sup>

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<sup>3</sup> The one document sought to be sealed that is not attached as an exhibit to a court filing was cited and discussed in a court filing.

<sup>4</sup> Nor did the ZHP Parties seek to seal documents that Plaintiffs challenged in their November 18, 2020 letter. (*See* Ex. P to Plaintiffs’ Brief in Opp. to Mot. to Seal (ECF No. 988-16.) As a consequence, Plaintiffs have proffered those documents, which are no longer to be treated as

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9. The ZHP Parties' motion is supported by a detailed index, as required

by Local Rule 5.3(c), identifying the material to be sealed, the basis for sealing, the injury that may result if sealing is denied, why a less restrictive alternative to sealing is not appropriate, and the bases for Plaintiffs' opposition to sealing. (Ex. A to Bonner Declaration, ECF No. 859-5.) Also submitted in support of the Motion to Seal as part of ECF No. 859-5 are Declarations of the following ZHP custodians: Jucai Ge (Ex. B); Jie Wang (Ex. C); Mi Xu (Ex. D); Jun Du (Ex. E); Minli Zhang (Ex. F); Linda Lin (Ex. G); and Eric Gu (Ex. H).

10. Plaintiffs' opposition to the Motion includes not only the documents for which the ZHP Parties waived their confidentiality designations, (ECF No. 988-2 through 988-8), but also documents designated by a co-defendant that the Court determined should be publicly accessible. (ECF No. 988-9 through 988-13.) *See In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Prods. Liab. Litig.*, --- F. Supp. 3d ----, 2021 WL 75258, at \*6 (D.N.J. Jan. 8, 2021).

Plaintiffs argue that the 29 documents that are the subject of the motion to seal are similar in nature to the documents that are not protected, either because the confidentiality designation was waived by the ZHP Parties or because Judge Schneider found that they did not qualify as confidential material.

11. The Third Circuit has identified the following as a non-exhaustive and non-mandatory list of factors to consider when deciding a motion to seal:

a. Whether disclosure would violate any privacy interests;

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confidential, as comparators to the documents that the ZHP Parties now seek to seal.

- e. whether the information is being sought for a legitimate purpose or for an improper purpose;
- c. whether disclosure would cause a party embarrassment;
- d. whether confidentiality is being sought over information important to public health and safety;
- e. whether the sharing of information among litigants will promote fairness and efficiency;
- f. whether a party benefitting from the order of confidentiality is a public entity or official; and
- g. whether the case involves issues important to the public.

*In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 924 F.3d 662, 670 (3d Cir. 2019) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995)).

12. The Third Circuit has also held that “where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law.” *Pansy v. Stroudsburg*, 23 F. 3d 772, 791 (3rd Cir. 1994).

13. The foregoing factors are applied in the context of materials that are not part of the “court record.” However, a “more rigorous common law right of access” applies when, as here, the discovery materials are filed with the court. *Avandia*, 924 F.3d at 670. “In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access.” *Id.* (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)).

14. “Analytically distinct from the District Court’s ability to protect discovery materials under Rule 26(c), the common law presumes that the public has a right of access to judicial materials. In both criminal and civil cases, a common law right of access attaches ‘to judicial proceedings and records.’” *In re Avandia*, 924 F.3d at 672.

15. The common law right of access applies to a “judicial record.” A “judicial record” is a document that “has been filed with the court . . . or otherwise somehow incorporated or integrated into a district court’s adjudicatory proceedings.” *Avandia*, 924 F.3d at 672. “Once a document becomes a judicial record, a presumption of access attaches.” *Id.*

16. “The party seeking to overcome the presumption of access bears the burden of showing ‘that the interest in secrecy outweighs the presumption.’ The movant must show ‘that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.’” *Id.*

17. As explained in *Avandia*, 924 F.3d at 672-73 (citations, internal alterations, and quotation marks omitted; emphasis added):

To overcome that strong presumption, the District Court must articulate the compelling, countervailing interests to be protected, make specific findings on the record concerning the effects of disclosure, and provide an opportunity for interested third parties to be heard. In delineating the injury to be prevented, specificity is essential. *Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.* Careful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants. To that end, the District Court must conduct a document-by-document review of the contents of the



18. Each of the challenged twenty-nine documents has been reviewed with these principles in mind.<sup>5</sup> There follows a document-by-document review of the contested designations.<sup>6</sup>

**1. ZHP00305868 (ECF No. 638, Ex. 4)**<sup>7</sup>: A supplier report dated January 31, 2018, designated as “CONFIDENTIAL INFORMATION.” The supplier stipulated that this material is an “internal confidential document” that is not to be forwarded or disseminated without the authorization of the supplier. ZHP has submitted the declaration of Jucai Ge, who asserts that making this document publicly accessible “would violate ZHP’s confidentiality agreement with [the supplier], which prohibits the disclosure of confidential information absent reasonable advance notice and compelling applicable law.” (Doc. 859-5 at 33.) Ge further asserts that disclosure “likely would result in significant financial harm in the form of litigation costs and damages,

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<sup>5</sup> The ZHP Parties have divided the documents at issue into three categories: (1) “nonpublic, proprietary technical information, protocols, and processes relating to the research, development, formulation, and manufacture of the ZHP Parties’ APIs and drug products, which are presently unavailable to the public,” (2) “FDA establishment inspection reports of the ZHP Parties’ manufacturing facilities,” and (3) “customer communications.” (ECF 859-4 ¶¶ 16, 24, 29). This categorization does not obviate a document-by-document review of the documents at issue on the motion to seal.

<sup>6</sup> It is hoped that this detailed approach will provide the parties guidance on future designations of confidentiality and challenges under the Protective Order.

<sup>7</sup> Each of the documents at issue is identified by its Bates Number along with the ECF Number of the court filing to which it is attached as well as the Exhibit designation given to it by Plaintiffs. In addition, ZHP’s specific confidentiality designation is noted.

and jeopardize ZHP's relationship with its customer.” Plaintiffs

counter by observing that Judge Schneider has previously ruled that a party’s own designation of a document as confidential is not controlling, citing *Valsartan*, 2021 WL 75258, at \*6. But the confidentiality designation at issue here is not ZHP’s. Instead a third party has designated the report confidential, and ZHP’s representation that disclosure would harm its relationship with the third party has not been refuted. One of the factors to consider in deciding whether to seal a document is the privacy interests of third parties. Here, the third party’s designation of the document as confidential coupled with ZHP’S representation that disclosure would harm its relationship with the third party suffice to overcome the presumption of public access. Accordingly, the motion to seal this document will be granted.<sup>8</sup>

**2. ZHP00385769 (ECF No. 638, Ex. 5):** An internal “deviation investigation report,” dated August 27, 2018, designated “RESTRICTED CONFIDENTIAL INFORMATION,” which concerns genotoxic impurity of valsartan.<sup>9</sup> ZHP seeks to seal this document on

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<sup>8</sup> ZHP also sought to seal this document on the basis that its disclosure would harm it competitively by causing confusion among its customers that could be exploited by ZHP’s competitors. This speculative possibility, however, does not warrant sealing a document that has implications for the safety of ZHP’s product. *See Valsartan*, 2021 WL 75258, at \*3.

<sup>9</sup> “The primary purpose of a deviation investigation report in a [Good Manufacturing Practice] environment is to clearly and concisely demonstrate that the root cause of the deviation has been identified; corrective actions have been taken; and that safety, integrity, strength (potency), purity, and quality (SISPQ) of the product has been ensured.” P. Drapala, “Deviation Investigation Format and Content: A Guide for Inspection Success,”

the grounds that it “details proprietary manufacturing information,

composition, formation steps, and solvents used for multiple different drugs, as well as proposed process changes.” (Doc. 859-5 at 3.)

Examination of the document, however, does not substantiate these assertions. Specifically, details of the manufacturing processes are not disclosed. Furthermore, the document is similar to other documents concerning the nitrosamine contamination of valsartan that have not been sealed in this litigation. *See, e.g.*, Ex. C to Plaintiffs’ Brief in Opp. to Mot. to Seal, August 8, 2018 Amended Form FDA 483, Inspectional Observations, ECF No. 988-3. Given the significant public interest in the health and safety of pharmaceutical products and the lack of detailed manufacturing process information presented in this court record, the motion to seal this document will be denied.

- 3. ZHP00479762 (ECF No. 638, Ex. 7):** Customer communications, designated by ZHP as “RESTRICTED CONFIDENTIAL INFORMATION,” concerning impurities and “unknown peaks” found in testing of valsartan. While ZHP seeks to shield these communications on the ground that they “reveal proprietary specifications and testing methods for impurities,” (Doc. 895-5 at 4), such information is not apparent on the face of the documents.

Furthermore, the documents reflect communications with ZHP

customers and no showing has been made that the customers are obligated to treat the communications as confidential. Accordingly, the motion to seal this document will be denied.

**4. ZHP00493010 (ECF No. 638, Ex. 8):** Communications between the ZHP Parties and a customer, designated by ZHP as “RESTRICTED CONFIDENTIAL INFORMATION,” that concerns unknown peaks for some residual solvents testing. ZHP seeks to seal these communications on the ground they describe “proprietary chromatography testing methods and procedures.” (ECF No. 859-5 at 5.) In support of this position, ZHP has submitted the declaration of Mi Xu (ECF No. 859-5 at 42). Xu states that “ZHP's chromatogram testing results and investigation as to the cause of unknown peaks are highly sensitive commercial information that would cause ZHP significant harm if revealed to its competitors and customers.” (*Id.* at 43.) Plaintiffs assert that the email exchanges do not discuss the testing in detail. The email string does, however, reveal substances found in the chromatography testing, and ZHP has represented that such information “would cause significant competitive harm by allowing [competitors] to reap the benefits of research and development. . . .” The presumption of public access to this court-filed document, coupled with the public safety dimensions of this case, however, tips the scale against sealing

this document. See *Avencha*, 924 F.3d at 676; *In re: Benicar (Olmesarten) Products Liab. Litig.*, 15-2606 (RBK/JS), 2016 WL 266353, at \*3 (D.N.J. Jan. 21, 2016) (“Where the materials in question relate to ‘information important to public health and safety’ confidentiality is disfavored.”). Ultimately, this factor compels denial of the request to seal this document.

**5. ZHP00423144 (ECF No. 638, Ex. 6):** Customer communications

designated as “CONFIDENTIAL INFORMATION.” As described in the declaration of Jie Wang, this email exchange concerned testing for genotoxic impurities in valsartan destined for Brazilian and European markets. Wang asserts that disclosure of the communications would “result in confusion among downstream consumers, and diminished sales.” (Doc. 859-5 at 39.) This is not the type of harm that rebuts the presumption of public access to this court record. See *Benicar*, 2016 WL 266353 at \*3 (That a document may be read out of context and damage a manufacturer’s reputation does not warrant sealing a court record.). Accordingly, the motion to seal this document will be denied.

**6. PRINBURY00129588 (ECF No. 685, Ex. B):** A draft response to

inspection observations by the FDA designated “RESTRICTED CONFIDENTIAL INFORMATION.” This draft document was not intended for public dissemination, and according to the Declaration of Jucai Ge, disclosure of the draft response now could cause confusion

among ZHP's customers that ZHP competitors could exploit. Such

speculative harm, however, is not enough to defeat the presumption of public access. *See id.* Accordingly, the motion to seal this document will be denied.

**7. ZHP00076700 (ECF No. 685, Ex. C):** Communications between the

ZHP Parties and their tax preparer for purposes of obtaining tax advice, which have been designated "CONFIDENTIAL INFORMATION."

These communications have nothing to do with the merits of this matter, but have been presented to show that ZHP had a detailed ZHP organization chart in English weeks before a meeting with Plaintiffs and Judge Schneider, at which ZHP produced organization charts in Chinese that failed to show ZHP General Manager Baohua Chen's central involvement in ZHP, Shanghai Syncores, and other ZHP subsidiaries.

The document now is considered a court record, and no showing has been made to overcome the presumption of public access. In this regard, the communications do not reveal confidential financial information. Relevance *vel non* is not being assessed in determining whether a document that is now part of the court record in this matter should be sealed. The fact that the document has been presented in connection with an issue to be resolved by the court implicates the right of public access. Accordingly, the motion to seal this document will be denied.

**8. PRINSTON00083640 (ECF No. 685, Ex. E):** FDA pre-approval

establishment inspection report for the period June 24, 2019 through June 28, 2019 designated as “RESTRICTED CONFIDENTIAL INFORMATION.” According to the Declaration of Minli Zhang, this document “evaluates ZHP’s readiness to operate as the commercial manufacturer of Rocuronium Bromide—a product that is not at issue in this litigation—and describes in extensive detail ZHP’s manufacturing operations and standard operating procedures.” Unrebutted, however, is Plaintiffs’ assertion that “[t]his is an FDA document redacted in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that Act.” (Doc. 859-5 at 53.) If the public can access this document in its present form, it is difficult to conceive how it may nonetheless be sealed. *See Pansy*, 23 F.3d at 791 (“where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law.”). ZHP has not addressed this anomaly, and its motion to seal this document will be denied.<sup>10</sup>

**9. PRINSTON00077836 (ECF No. 685, Ex. F):** Excerpts from a

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<sup>10</sup> It is hoped that the parties will follow this determination with respect to other documents for which the FDA has made FOIA determinations and, to the extent that the FDA has found that the documents are subject to production on a FOIA request, de-designate the documents as confidential.

CONFIDENTIAL INFORMATION.” The Declaration of Linda Lin states that this document “details ZHP's proprietary manufacturing unities, equipment, quality assurance, and manufacturing operations for valsartan.” (ECF No. 859-5 at 59.) To the extent that Lin’s Declaration describes the entire document, sealing would be warranted. But the document attached to ECF No. 685 as Ex. F is only an excerpt of a larger document, and the only information in the excerpt submitted to the Court is a list of ZHP personnel associated with the production of valsartan. Sealing that information is not warranted. Accordingly, ZHP’s motion to seal Ex. F to ECF No. 685 will be denied.

**10. PRINSTON00082994 (ECF No. 685, Ex. H):** Excerpts from an FDA establishment inspection report dated August 9, 2013, designated “RESTRICTED CONFIDENTIAL INFORMATION.” Plaintiffs have represented that the excerpt is limited to that part of the report made accessible by the FDA in accordance with the Freedom of Information Act (“FOIA”). The motion to seal will be denied to the extent that the document is limited to that which the FDA has determined should be publicly accessible.

**11. ZHP00107709 (ECF No. 685, Ex. I):** Excerpts from an FDA establishment inspection report dated August 13, 2014, designated “RESTRICTED CONFIDENTIAL INFORMATION.” The document



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is limited to that which the FDA has determined should be publicly accessible under FOIA. Accepting this uncontroverted representation from Plaintiffs as accurate, the motion to seal this document will be denied.

**12. PRINSTON0074125 (ECF No. 685, Ex. J):** Excerpts from an FDA establishment inspection report dated August 13, 2014, designated “RESTRICTED CONFIDENTIAL INFORMATION.” The document is limited to that which the FDA has determined should be publicly accessible under FOIA. Accepting this uncontroverted representation from Plaintiffs as accurate, the motion to seal this document will be denied.

**13. PRINSTON00083026 (ECF No. 685, Ex. K):** Excerpts from an FDA establishment inspection report dated September 14, 2015, designated “RESTRICTED CONFIDENTIAL INFORMATION.” As represented by Plaintiffs, the excerpts are limited to that which the FDA has determined are publicly accessible under FOIA. Accepting this uncontroverted representation from Plaintiffs as accurate, the motion to seal this document will be denied.

**14. PRINSTON00081549 (ECF No. 685, Ex. L):** Excerpts from an FDA inspection report dated January 17, 2017, designated as “RESTRICTED CONFIDENTIAL INFORMATION.” As represented by Plaintiffs, the excerpts are limited to that which the FDA has determined are publicly

from Plaintiffs as accurate, the motion to seal this document will be denied.

**15. PRINSTON00081570 (ECF No. 685, Ex. N):** Excerpts from an FDA inspection report dated April 10, 2018, designated as “RESTRICTED CONFIDENTIAL INFORMATION.” As represented by Plaintiffs, the excerpts are limited to that which the FDA has determined are publicly accessible under FOIA. Accepting this uncontroverted representation from Plaintiffs as accurate, the motion to seal this document will be denied.

**16. ZHP0000215 (ECF No. 685, Ex. P):** A 2010 business agreement between ZHP and Shanghai Syncores, designated as “RESTRICTED CONFIDENTIAL INFORMATION.” The Declaration of Eric Gu, general manager of Shanghai Syncores, represents that “[b]ecause the agreement details ZHP's proprietary manufacturing processes prior to implementation, and reveals ZHP’s development costs, the disclosure of this information to ZHP’s direct competitors would cause significant competitive harm.” Although Plaintiffs assert that public health concerns predominate over ZHP’s business interests, they do not explain how unsealing this document will advance public understanding of the valsartan contamination. Accordingly, the motion to seal this document will be granted.

**17. ZHP02579748 (ECF No. 685, Ex. Q):** Internal meeting notes, entirely

INFORMATION.” The Declaration of Linda Lin represents that “[t]his document contains internal notes on a meeting regarding API process optimization. Details of ZHP's API processes are highly sensitive, proprietary commercial information.” (ECF No. 859-5 at 60.) She contends that “[d]isclosure of ZHP’s API process optimization strategies to ZHP’s direct competitors would result in significant competitive harm by allowing them to benefit from ZHP’s proprietary research and development while the FDA restricts ZHP from exporting its products into the U.S. market.” (*Id.*) Plaintiffs do not contest ZHP’s characterization of the meeting notes, but instead speculate that eight year-old notes do not pose a competitive threat to ZHP. Finding that ZHP has sufficiently rebutted the presumption of public access by making a specific showing of competitive harm, the motion to seal this document will be granted.

- 18. ZHP00494048 (ECF No. 685, Ex. S):** An internal protocol governing the ZHP parties’ recall of foreign-grade valsartan API. The Ge declaration contends that disclosure of ZHP’s recall protocol would cause it significant competitive harm. (ECF No. 859-5 at 35.) A close examination of the document, however, reveals the type of common sense, generic information expected of any product recall. Given the presumption of public access to this court record and its apparent lack of proprietary, confidential information, ZHP’s motion to seal this document will be

**19. PRINSTON00162373 (ECF No. 685, Ex. R):** A redacted excerpt from an FDA establishment inspection report documenting the FDA's inspection of the ZHP Parties' manufacturing facility for the period of July 23, 2018 through August 3, 2018, designated "RESTRICTED CONFIDENTIAL INFORMATION." As represented by Plaintiffs, the excerpts are limited to that which the FDA has determined are publicly accessible under FOIA. Accepting this uncontroverted representation from Plaintiffs as accurate, the motion to seal this document will be denied.

**20. ZHP00458585 (ECF No. 685, Ex. T):** Communications between ZHP and its customer designated "RESTRICTED CONFIDENTIAL INFORMATION." The Declaration of Mi Xu contends that disclosure of the testing information exchanged in these communications could cause confusion among ZHP's customers, resulting in significant commercial and financial harm. (ECF No. 859-5 at 43.) Plaintiffs counter by stating that the public's interest in understanding the causes of nitrosamine contamination of ZHP's product, greatly outweighs ZHP's interest in confidentiality. In this regard, "[r]eputational harm must be specifically identified and particularly serious to merit consideration as a legitimate private interest." *Benicar* 2016 WL 266353, at \*5. ZHP has not shown how this information would cause customer confusion and has not shown that such confusion would be sufficiently serious to warrant denying public

access to this court record. The Xu Declaration also points to the confidentiality legend on the email exchange as signifying that ZHP's customer expected confidentiality with respect to this exchange. However, "a party's classification of material as protected or confidential does not automatically satisfy the criteria for sealing pursuant to Local Civil Rule 5.3." *Id.* at \*3. With respect to this email exchange, the public interest in the contamination of valsartan plainly outweighs the private interest in confidentiality. Accordingly, the motion to seal this document will be denied.

**21. ZHP00476678:** Customer communications from May 2015 designated "CONFIDENTIAL INFORMATION." The Declaration of Me Wang states that "[t]his exchange reveals ZHP's confidential communications with its customer regarding its specifications and documentation requirements. If disclosed, this information would result in the loss of proprietary information regarding the specifications of ZHP and competitive harm to their customer by needlessly exposing their product information and jeopardize ZHP's relationship with its customer." (ECF No. 859-5 at 40.) The document itself, however, is a routine business communication about general documentation requirements for a transaction. No product specification are revealed. ZHP, therefore, has not rebutted the presumption of public access to this court record. Accordingly, the motion to seal this document will be denied.

**22. ZHP02270194 (ECF No. 685, Ex. U):** Customer communications

designated “RESTRICTED CONFIDENTIAL INFORMATION.” The Declaration of Mi Xu states that these “communications with ZHP’s customers regarding ZHP’s sales targets and forecasts are highly sensitive, and reflect proprietary sales and forecasting data, which, if disclosed to ZHP’s direct competitors, would result in significant financial harm.” (ECF No. 859-5 at 40.) Plaintiffs’ rejoinder relies upon the age of the communication (about 4 years old) to argue that its disclosure could not cause the harm alleged. In light of the business and proprietary nature of the information contained in the communications, the presumption of public access has been rebutted. Accordingly, the motion to seal this document will be granted.

**23. ZHP01893902 (ECF No. 685, Ex. V):** Customer communications

designated “CONFIDENTIAL INFORMATION.” The Xu Declaration asserts that “communications with its customers regarding order status and monthly sales data are highly sensitive.” (ECF No. 859-5 at 44.) This document may have merited sealing if it in fact contained such information, but it does not. It is simply an invitation to a sales planning meeting. Accordingly, the motion to seal this document will be denied.

**24. ZHP00310874 (ECF No. 685, Ex. W):** Customer communications

designated “RESTRICTED CONFIDENTIAL INFORMATION.” The exchange reveals chromatography testing, sampling, and investigation

results reported by a ZHP customer. The Xu Declaration asserts that

disclosure of this information without authorization from its customer

would violate a confidentiality agreement and cause ZHP financial harm.

(ECF No. 859-5 at 45.) But the information has already been disclosed in

the context of this litigation. Moreover, the information revealed in these

communications concern only testing results, not testing methods or

procedures. In light of the presumption of public access to court records,

the motion to seal this document will be denied.

**25. ZHP02125655 (ECF No. 685, Ex. X):** Customer communications

designated “RESTRICTED CONFIDENTIAL INFORMATION.” This

exchange is with the same customer at issue in paragraph 24 above and

reveals information about chromatography testing for unknown peaks in

ZHP’s valsartan. For the reasons sealing was denied as to the documents

in paragraph 24 above, sealing will be denied as to this document.

**26. ZHP01976459 (ECF No. 685, Ex. Z):** Invitation for monthly meeting

with ZHP customer. No business or technical information is mentioned.

The Xu Declaration asserts that disclosure of sales targets and other

information would be damaging, but no such information is disclosed in

this document. Accordingly, the motion to seal this document will be

denied.

**27. HUAHAI-US00008050 (ECF No. 685, Ex. AA):** Customer

communications designated “CONFIDENTIAL INFORMATION.” The

communications concern an audit of a ZHP facility, but no proprietary or other confidential information is revealed. The only information disclosed pertains to the duration of a site visit and the matters to be addressed in the audit. Given the presumption of public access to this court record, the motion to seal will be denied.

**28. ZHP00183600 (ECF No. 705):** An audit plan of the ZHP Parties’

Chuannan site for the period of June 13-14, 2017 designated “RESTRICTED CONFIDENTIAL INFORMATION.” The document consists largely of unanswered questions to be covered by audit. No financial, technical, or proprietary information is disclosed. The motion to seal this document will be denied.

**29. ZHP00182575 (ECF No. 705):** Communications designated

“RESTRICTED CONFIDENTIAL INFORMATION.” This email exchange reveals testing methods and details. Wang’s Declaration attests that “this information would cause significant competitive harm to both the ZHP Defendants and their customer by needlessly exposing their proprietary testing procedures to their direct competitors, placing them at a competitive disadvantage and wiping out their investment in researching and developing these procedures.” A review of the document confirms Wang’s description of its contents, and his Declaration suffices to constitute the “particularized showing that disclosure will cause a clearly defined and serious injury to the party seeking closure.” *Benicar*, 2016



WL 266353, at \*1. Accordingly, the motion to seal this document will be

granted.

Pursuant to the foregoing Findings and for good cause shown:

**IT IS** on this 24<sup>th</sup> day of May, 2021, **HEREBY**

**ORDERED** that the ZHP Parties' Motion to Seal (ECF No. 859) is hereby **GRANTED IN PART AND DENIED IN PART AS FOLLOWS:**

The following five documents shall be sealed:

ZHP00305868 (ECF No. 638, Ex. 4); ZHP0000215 (ECF No. 685, Ex. P);

ZHP02579748 (ECF No. 685, Ex. Q); ZHP02270194 (ECF No. 685, Ex. U);

and ZHP00182575 (ECF No. 705)

**IT IS FURTHER ORDERED** that in all other respects the ZHP Parties' motion to seal is **DENIED**.

**s/ Thomas I. Vanaskie**

Hon. Thomas I. Vanaskie (Ret.)

Special Master